OAH 65-2600-32428
Revisor R-4247

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of the Proposed Permanent Rules of the Minnesota Racing Commission Related to Horse Racing, Stabling, Class C Licenses, Horse Medications, Physical Examinations, and Medical Testing, Minn. R. Parts 7876, 7877, 7890, 7891, and 7892.

ORDER ON REVIEW OF RULES UNDER MINN. STAT. § 14.26

The Minnesota Racing Commission (Commission) seeks review and approval of the above-entitled rules, which were adopted by the Commission pursuant to Minn. Stat. § 14.26 (2014).

On April 17, 2015, the Office of Administrative Hearings (OAH) received the documents that must be filed by an agency under Minn. Stat. § 14.26 and Minn. R. 1400.2310 (2013). Additional documentation consisting of a Certificate of Additional Notice was filed on April 29, 2015.

Based upon a review of the submissions and the rulemaking record and for the reasons set forth in the Memorandum below,

IT IS HEREBY DETERMINED THAT:

1. The Commission has statutory authority to adopt the rules pursuant to Minn. Stat. §§ 240.03, .23, .24 (2014).

2. Despite the Commission's failure to fully comply with its Additional Notice Plan, the rules were adopted in substantial compliance with the procedural requirements of Minnesota Statutes Chapter 14 (2014), and Minnesota Rules Chapter 1400 (2013).

3. The record demonstrates that the rules are needed and reasonable, with the exception of Parts 7877.0175, subp. 8; 7890.0100, subp. 7a; and 7890.0110, subp. 12, item C.

4. Parts 7877.0175, subp. 8; 7890.0100, subp. 7a; and 7890.0110, subp. 12, item C, are **DISAPPROVED** as not meeting the requirements of Minn. R. 1400.2100, item B, as explained in the memorandum below.

5. All remaining rules are **APPROVED**, subject to some minor recommended changes to improve clarity**.**

IT IS HEREBY ORDERED THAT:

1. For the reasons set forth in the attached memorandum, Parts 7877.0175, subp. 8; 7890.0100, subp. 7a; and 7890.0110, subp. 12, item C, are **DISAPPROVED**.

2. Pursuant to Minn. Stat. § 14.26, subd. 3(b) and Minn. R. 1400.2300, subp. 6, the disapproved rules will be submitted to the Chief Administrative Law Judge for review.

3. All other rules are **APPROVED.**

4. It is respectfully recommended that the Commission consider making minor changes to Parts 7890.0100, subp. 18a; 7890.0110, subp. 9, item F; 7890.0110, subp. 10; and 7890.0110, subp. 11, item B, to increase clarity, as set forth in the memorandum below.

Dated: May 1, 2015

s/Ann C. O'Reilly
ANN C. O'REILLY
Administrative Law Judge

MEMORANDUM

Rules submitted to the Office of Administrative Hearings for review without a hearing are evaluated pursuant to Minn. Stat. § 14.26 and Minn. R. 1400.2100, .2300. According to Minn. Stat. § 14.26, subd. 3, the Administrative Law Judge shall approve or disapprove a rule based upon its "legality and form." This analysis includes determining whether the rule, if modified, is substantially different than originally proposed; whether the agency has authority to adopt the rules; whether the agency has fulfilled all relevant procedural requirements of rule and law; and whether the record demonstrates a rational basis for the need for and reasonableness of the proposed rule.[1]

The rules applicable to administrative review require that the Administrative Law Judge evaluate a proposed rule on eight specific grounds, namely, whether the rules:

[1] Minn. Stat. §§ 14.26, subd. 3; .50.

(1) were adopted in compliance with the procedural requirements of Minn. R. ch. 1400, Minn. Stat. ch. 14, and any other applicable law or rule;

(2) are rationally related to the agency's objectives and whether the record demonstrates the need for and reasonableness of the rules;

(3) are substantially different from the proposed rules, and whether the agency followed the procedures set forth in Minn. R. 1400.2110;

(4) exceed, conflict with, do not comply with, or grant the agency discretion beyond that which is allowed by the enabling statute or other applicable law;

(5) are unconstitutional or illegal;

(6) improperly delegate the agency's power to another agency, person, or group;

(7) are not "rules" as defined by Minn. Stat. § 14.02, subd. 4, or by their own terms cannot have the force and effect of law; and

(8) were adopted without compliance with Minn. Stat. §§ 14.25, subd. 2; 14.001(2), (4), (5), related to withdrawal of requests for hearing.[2]

If a proposed rules meets each of these criteria, they shall be approved by the Administrative Law Judge.

FAILURE TO FULFILL ADDITIONAL NOTICE PLAN

Minnesota Statutes section 14.14, subdivision 1a, provides that each agency shall maintain a list of all persons who have registered with the agency for purposes of receiving notice of rulemaking proceedings. In addition to maintaining this list, "each agency shall make reasonable efforts to notify persons or classes of persons who may be significantly affected by the rule being proposed by giving notice of its intention" to adopt rules.[3] This provision requires that an agency search beyond those on its mailing list to find groups of individuals or entities that may be particularly impacted by the proposed rules. This is what is referred to as an "Additional Notice Plan."

An agency may, but is not required to, submit an Additional Notice Plan for approval by an Administrative Law Judge.[4] The purpose of seeking approval of the Additional Notice Plan is to avoid potential issues in the approval of proposed rules because of a failure to provide notice to those who may be impacted by the rules. In this case, the Commission did not submit for approval its Additional Notice Plan. Instead, it

[2] Minn. R. 1400.2100.
[3] Minn. Stat. § 14.14, subd. 1a.
[4] Minn. R. 1400.2060.

included the Additional Notice Plan in its Statement of Need and Reasonableness (SONAR).

Regardless of whether an agency seeks approval of its Additional Notice Plan, Minn. R. 1400.2310 provides that an agency must file either a Certificate of Additional Notice or a copy of the transmittal letter to the parties noticed. Rule 1400.2310 also requires that the agency submit "any other document or evidence to show compliance with any other law or rule which the agency is required to follow in adopting [the] rule." Therefore, the Commission was required to provide documentation that it complied with its Additional Notice Plan.

The record in this case does not establish that the Commission fully complied with its Additional Notice Plan. According to the Additional Notice Plan contained in the SONAR, the Commission asserted that it would:

1. Publish the Request for Comments in the September 2, 2014 edition of the *State Register.*

2. Post the Request for Comments and the language of the proposed rules on the Commission's website.

3. Mail or e-mail the Request for Comments to Class A and B licensees, as well as horsemen's associations that are affected by horse racing in Minnesota, including the Minnesota Thoroughbred Association, the Horsemen's Benevolent and Protective Association, Minnesota Harness Racing, Inc., the Minnesota Quarter Horse Racing Association, the Jockey's Guild, and the United States Trotting Association.

4. Mail or e-mail the Request for Comments to organizations identified as having an interest in animal health including the Minnesota Board of Animal Health, the Minnesota Humane Society, the Minnesota Veterinary Medical Association, and the University of Minnesota College of Veterinary Medicine.

5. Mail the rules and Notice of Intent to Adopt to everyone who has registered to be on the Commission's rulemaking list under Minn. Stat. § 14.14, subd. 1a.

6. Give notice to the Legislature pursuant to Minn. Stat. § 14.116.

7. Publish the proposed rules and Notice of Intent to Adopt in the *State Register*.

8. Provide a copy of the rules and Notice of Intent to Adopt Rules to Class A and B licensees, the horsemen's organizations listed in paragraph 3 above, and the animal health entities listed in paragraph 4 above.[5]

The record establishes that the Commission complied with paragraphs 1, 5, 6, and 7 above. While the Commission did not include evidence of the posting of items to the agency's website, the Administrative Law Judge was able to determine that the postings described in paragraph 2 above were completed.

On April 29, 2015, at the request of the Administrative Law Judge, the Commission filed a Certificate of Additional Notice (Certificate) affirming that on March 6, 2015 or March 9, 2015, the Commission mailed or e-mailed the Notice of Intent to Adopt Rules and a copy of the proposed rules on Class A and B Licenses (Canterbury Park and Running Aces Harness Park); the Minnesota Thoroughbred Association; the Horsemen's Benevolent and Protective Association; Minnesota Harness Racing, Inc.; the Minnesota Quarter Horse Racing Association; the Jockey's Guild; the United States Trotting Association; the Minnesota Board of Animal Health; the Minnesota Humane Society; and the University of Minnesota College of Veterinary Medicine. The Minnesota Veterinary Medical Association was not included in this service, contrary to what was contemplated by the Commission's Additional Notice Plan.

In addition, the Commission provided no evidence that it fulfilled its Additional Notice Plan by mailing or e-mailing the Request for Comments on Class A and B licensees; the Minnesota Thoroughbred Association, the Horsemen's Benevolent and Protective Association; Minnesota Harness Racing, Inc.; Minnesota Quarter Horse Racing Association; the Jockey's Guild; the United States Trotting Association; the Minnesota Board of Animal Health; the Minnesota Humane Society; the University of Minnesota College of Veterinary Medicine; or the Minnesota Veterinary Medical Association. The Commission only provided evidence that it published the Request for Comments in the *State Register* on September 2, 2014. Therefore, the record does not establish that the Commission fully complied with its own Additional Notice Plan.

The law provides that the Administrative Law Judge shall disregard any error or defect in the proceeding due to an agency's failure to satisfy procedural requirements imposed by law or rule if the Administrative Law Judge finds that the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process.[6] Here, the Commission's failure to fully comply with its own Additional Notice Plan did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process.

With the exception of the Minnesota Veterinary Medical Association, the Commission served the identified interested parties with a Notice of Intent to Adopt Rules and the proposed rules. Thus, notwithstanding the fact that some affected parties did not receive notice of the Request for Comments, as described in the Additional Notice Plan,

[5] SONAR at 4.
[6] Minn. Stat. §§ 14.15, subd. 5(1); .26, subd. 3(d)(1).

the affected parties were provided with notice of the Commission's intent to adopt the rules and the rules themselves. Such notice was sufficient to give the interested parties a meaningful opportunity to participate in the rulemaking proceeding.

In addition, the Commission timely published the Request for Comments, Notice of Intent to Adopt Rules, and proposed rules in the *State Register*, thereby notifying all those who did not receive direct notice. The Commission further asked four of the local horsemen's organizations to publish a statement about the Commission's intent to adopt rules in their newsletters and communications to their members.

The proposed rules affect race horses and race horse owners, trainers, and veterinarians that specially treat race horses. Veterinarians who treat race horses are a small subset of the veterinarians who are members of the Minnesota Veterinary Medical Association. The small group of veterinarians who treat race horses are hired or employed by the Commission, the Class A and B licensees, and/or the members of the horsemen's organizations, all of whom were provided ample notice of the rules.

Because the members of the horsemen's organizations work closely with their veterinarians to ensure that their horses are cared for and meet all racing requirements, it is likely that all affected veterinarians were made aware of the rules as part of the notice served upon the Class A and B licensees and the horsemen's organizations. Thus, while the Commission did not fully comply with its Additional Notice Plan, its failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process.

Notice to affected parties and the public is an integral part of the rulemaking process. Without adequate notice and the ability to meaningfully participate, the integrity, quality, and public confidence in rulemaking is diminished. Widespread notice of rulemaking proceedings increases public accountability, public participation in the formulation of rules, public access to governmental information, and fairness of agency conduct – all stated purposes of the Administrative Procedure Act.[7] Therefore, it is important that agencies substantially comply with all notice requirements and provide documentation of the same in their rulemaking submissions.

TECHNICAL ISSUES WITH THE SONAR

Minnesota Statutes section 14.131 provides that a Statement of Need and Reasonableness include, among other things:

> [T]he probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individual.

While the SONAR does not directly state the costs of complying with the rule for the affected parties in its response to Section 14.131(5), the Commission does provide a

[7] *See* Minn. Stat. § 14.001.

response to this factor in other areas of the SONAR. Accordingly, the Administrative Law Judge was able to determine the probable costs to affected parties by piecing together other parts of the SONAR, rendering the defect harmless error. However, this is not an ideal way of presenting the required information or for fulfilling key purposes of the rulemaking process: specifically, "increase[ing] public access to governmental information" and "increasing public participation in the formation of administrative rules."[8] Nonetheless, the Administrative Law Judge brings this to the Commission's attention for purposes of future rulemaking submissions.

DISAPPROVED RULES

Part 7877.0175, subpart 8

Rule 7877.0175, subpart 8 addresses the circumstances under which a Commission or association veterinarian can provide emergency medical assistance to a horse on racetrack grounds. The intent of the disapproved provision in subpart 8 is to require the Commission or association veterinarian to attempt contact with the racehorse owner's veterinarian before providing care. The record establishes that such a provision is necessary for the humane treatment of race horses. The problem, however, is that three words in the proposed provision render the rule unreasonably vague.

The proposed changes to Rule 7877.0175, subp. 8 provide, in relevant part:

> In the event of a veterinary emergency where the owner's veterinarian is not on racetrack grounds or easily reachable, the commission veterinarian or association veterinarian may administer emergency treatment ~~on the request of~~ to a horse after consulting with the owner or owner's agent if they are present. In ~~such~~ all cases, the ~~owner is responsible for any costs incurred~~ owner's veterinarian will be notified and the case transferred to the owner's veterinarian as soon as the owner's veterinarian is present.

The added provision "or easily reachable" is too imprecise to administer and subjects the Commission to dispute or litigation. Whether an owner is "easily reachable" can be subject to a variety of interpretations. It is not clear, for example, how long the Commission/association veterinarian must wait for a return call before an owner's veterinarian is considered "not easily reachable"; or how many attempted telephone calls render a veterinarian "not easily reachable." The ambiguity caused by the "or easily reachable" provision renders the rule unreasonably vague. As a result, the rule must be **DISAPPROVED.**

To cure this defect, the Commission could simply delete the phrase "or easily reachable." This would be the preferred remedy. In the alternative, the Commission could clarify the phrase as follows:

> In the event of a veterinary emergency where the owner's veterinarian is not on racetrack grounds or is not available on the first attempted call to the

[8] Minn. Stat. § 14.001 (4), (5).

veterinarian at the telephone number provided to the commission by the horse's owner, veterinarian, or trainer, the commission veterinarian or association veterinarian may administer emergency treatment…

Neither of the cures would cause a substantial change in the proposed rule requiring additional notice.

Because the provision must be revised in order to be approved, the Administrative Law Judge further recommends that the Commission clarify the rule by the inclusion of the following words denoted by the double underscore:

> In the event of a veterinary emergency where the owner's veterinarian is not on racetrack grounds ~~or easily reachable~~, the commission veterinarian or association veterinarian may administer emergency treatment ~~on the request of~~ to a horse after consulting with the owner or owner's agent if they are present on racetrack grounds. In ~~such~~ all cases, the ~~owner is responsible for any costs incurred~~ owner's veterinarian will be notified and the case transferred to the owner's veterinarian as soon as the owner's veterinarian is present on racetrack grounds.

This recommended change is suggested to improve clarity and precision. If the Commission decides to accept this recommendation, this change to the rule would not be a substantial change requiring further review or approval by the Administrative Law Judge.

Part 7890.0100, subpart 7a

Part 7890.0100, subpart 7a provides a definition for "compounding" which would be both helpful and necessary for the rules, given the repeated use of the term in the proposed rules. However, the definition proposed by the Commission is inconsistent with existing law, and is unreasonably imprecise and vague. As a result, the rule provision is **DISAPPROVED**.

Proposed Rule 7890.0100, subpart 7a reads as follows:

> 'Compounding' means manipulation of a drug beyond that stipulated on the drug label.

The Commission asserts that its definition of "compounding" is consistent with the definition of "compounding" found in Minnesota Statutes applicable to the Board of Pharmacy. In the SONAR, the Commission states that:

> This proposed rule change provides a definition of the word compounding used by the Minnesota Board of Pharmacy. It is reasonable to add this definition as it is used in another proposed rule change.

Contrary to the Commission's assertions in the SONAR, the definition of "compounding" contained in the laws applicable to the Board of Pharmacy is not the same definition proposed by the Commission. Indeed, the two definitions are quite dissimilar.

The definition of "compounding" set forth in the Board of Pharmacy statutes, Minn. Stat. § 151.01, subd. 35 (2014), reads as follows:

> Subd. 35. **Compounding.**
>
> "Compounding" means preparing, mixing, assembling, packaging, and labeling a drug for an identified individual patient as a result of a practitioner's prescription drug order. Compounding also includes anticipatory compounding, as defined in this section, and the preparation of drugs in which all bulk drug substances and components are nonprescription substances. Compounding does not include mixing or reconstituting a drug according to the product's labeling or to the manufacturer's directions. Compounding does not include the preparation of a drug for the purpose of, or incident to, research, teaching, or chemical analysis, provided that the drug is not prepared for dispensing or administration to patients. All compounding, regardless of the type of product, must be done pursuant to a prescription drug order unless otherwise permitted in this chapter or by the rules of the board. Compounding does not include a minor deviation from such directions with regard to radioactivity, volume, or stability, which is made by or under the supervision of a licensed nuclear pharmacist or a physician, and which is necessary in order to accommodate circumstances not contemplated in the manufacturer's instructions, such as the rate of radioactive decay or geographical distance from the patient.

The Board of Pharmacy definition is significantly different from, and much more specific than, the definition proposed by the Commission. Because "compounding" is a technical term and, when used in a pharmaceutical sense, is one that is not subject to common understanding, it is important that a more precise definition be included in the rules.

The Commission apparently intends "compounding," for purposes of its rules, to mean the use of a drug in a manner different from, or inconsistent with, the use stated on the drug's label. However, the Commission's definition does not clearly convey this meaning. In particular, the use of the words "manipulation" and "stipulated" infuse ambiguity into the definition.

The Administrative Law Judge recommends that the Commission revisit this rule provision and resubmit a new definition consistent with an established and accepted medical or pharmaceutical definition. For example, a definition consistent with the Board of Pharmacy definition would be, "Compounding means preparing, mixing, assembling, packaging, and labeling a drug for an identified individual horse as a result of a veterinarian's prescription drug order."

In the alternative, the Commission could simply adopt the entire definition of "compounding" provided for in Minn. Stat. § 151.01, subd. 35, or adopt the Board of Pharmacy's definition by reference. Another alternative is to define "compounding" as "use of a drug or mediation in a manner different from, or inconsistent with, the use stated on the drug or medication's label." For any of the recommended alternatives, the change would not be a substantial change, given the Commission's reference to Minn. Stat. § 151.01, subd. 35, in the SONAR and the proposed definition. Thus, the change could be easily incorporated without the need for additional notification or review.

Part 7890.0110, subpart 12, item C.

Rule 7890.0110, subpart 12 prohibits compounded medications on association grounds. Item C specifically prohibits possession of an improperly labeled product. The provision contains two words which make the provision unreasonably unclear. Therefore, the rule must be **DISAPPROVED**.

Part 7890.0110, subpart 12, item C provides:

> C. Possession of an improperly labeled product by a veterinarian, trainer, groom, or any other licensee, *including labeling*, is considered a violation.[9]

The phrase "including labeling" appears to be misplaced. It is unclear whether the Commission simply erred by including the two words, or whether the Commission intended to prohibit veterinarians, trainers, grooms, and licensees from improperly labeling drugs. Either way, the words "including labeling" render the proposed provision unreasonably confusing and unclear.

To remedy the defect, the Commission can simply delete the words "including labeling." In addition, when remedying the defect, the Administrative Law Judge recommends that the Commission replace the word "product" with "medication" to make item C consistent with items A and B.

RECOMMENDED CLARIFICATIONS TO APPROVED RULES

With the exception of the rules specifically identified above, the Administrative Law Judge **APPROVES** the remainder of the proposed rules. The Administrative Law Judge respectfully recommends some minor technical changes to better clarify the proposed approved rules. The recommended changes are as follows:

> **Part 7890.0100, subp. 18a: Threshold.** "Threshold" means a concentration <u>of a substance</u> in the serum, plasma, or urine <u>of a horse</u> above which a laboratory reports a finding.

[9] Emphasis added.

Part 7890.0110, subp. 9

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F. methoxytyramine: 4 mcg/ml urine, free ~~.~~ and conjugated.

Part 7890.0110, subpart 10. Medications with regulatory limits. No medications, other than those listed in this subpart or found in part 7890.0100, subpart 13, items A to D, shall be allowed in the test sample of a horse. Serum or urine thresholds on the following medications shall not exceed those found in the Racing Commissioners International Schedule of Controlled Therapeutic Substances, RCI Chapter 11 and Chapter 25, which is incorporated by reference….

Part 7890.0110, subp. 11. Medical Labeling.

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B. Any drug or medication that is used or kept on association grounds and that, by federal or state law, requires a prescription must have been validly prescribed by a duly licensed veterinarian, and in compliance with the applicable statutes. All allowable medications must be labeled in accordance with state and federal laws, and shall have a prescription label that is securely attached and clearly ascribed to show the following….

The above recommendations would not result in any substantial changes to the rules. As a result, they would not require additional review or approval by the Administrative Law Judge.

A. C. O.